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10/716,877

11/20/2003

Hee Kyung Ju

912-42

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03/05/2007

NIXON & VANDERHYE, PC

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ARLINGTON, VA 22203

EXAMINER

HAIDER, SAIRA BANO

ART UNIT

PAPER NUMBER

1711

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
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3 MONTHS

03/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/716,877

Applicant(s)

JU ET AL.

Examiner

Saira Haider

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 17 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 13, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/8/2006
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 8, 2006 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukushima et al. (US Patent No. 3,871,570) in combination with Onouchi et al. (US Patent No. 4,898,781).
4. Fukushima teaches a process for preparing microcapsules, wherein core substance (active component) is encapsulated (Column:Lines::1:40-47). Specifically, the core substance may be either solid or liquid and either soluble or insoluble in the solvent utilized, one example includes an enzyme in a methylene chloride solvent (3:9-21, 2:38-59). The process comprising: dissolving a polymeric wall material in a solvent with a core substance, adding a vehicle (polyhydric alcohol or polyol), emulsifying the dispersion and obtaining microcapsules, evaporating the solvent, washing off the polyhydric alcohols, and obtaining hard polymer microcapsules (2:19-35, 3:25-67, 4:9-42, Example 1). Fukushima discloses that polystyrene is an example of a polymeric wall material, wherein polystyrene is a hydrophobic polymer (2:62-3:6).
5. Fukushima fails to teach the formation of a first solution containing one active component dissolved in a polyol/solvent solution, and subsequent addition to first solution a polymer solution

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(containing a wall-component polymer), wherein the polyol is comprised of a mixture of the claimed high and low molecular weight polyols.

6. Hence attention is directed towards the Onouchi reference, which discloses water-soluble microcapsules containing an enzyme as a core material. Specifically, Onouchi discloses that the enzymes are not independently encapsulated; rather they can be dispersed in a water-containing polyhydroxy compound, such as a polyol. Concrete examples of the polyhydroxy compound include low molecular weight polyethylene-polypropylene glycol. Onouchi teaches that the addition of water-containing polyhydroxy compound to dissolve or disperse the enzyme acts as a supporting substance for ensuring perfect coating of the microcapsules and enhances the stability of enzyme during storage (2:28-37, 4:1-5, 4:30-52).

7. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to first dissolve the core substance in a polyol solution and subsequently add a polymeric wall material solution, in the microcapsule formation process of Fukushima in combination with the teachings of Onouchi in order to enhance the stability of the core substance during storage.

8. Furthermore, changes in the sequence of process steps, specifically reversing the order of the prior art process steps has generally been recognized as not being sufficient to patentably distinguish over the prior art. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) Additionally, the selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. *In re Burbans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). In effect, the applicants' specification does not provide any new or unexpected results due to the order of completion of the process steps.

9. In reference to the limitation regarding the polyol comprising a mixture of high and low molecular weight polyols, it is noted that Onouchi exemplifies the usage of both low and high

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molecular weight polyols, with molecular weights of 1,000 and 5,000 g/mol, respectively (Examples 8 and 9). Even though Onouchi does not disclose utilization of the combination of the different molecular weight polyols, Onouchi discloses the utilization of two or more disclosed polyols (col. 4, lines 40-52). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the exemplified polyols (i.e. the low and high molecular weight polyols) in order to ensure perfect coating of the microcapsule and further enhance the stability of the enzyme (4:30-39).

10. Additionally, it is noted that case law holds that if there is no evidence in the record pointing to any critical significance in a claimed molecular weight then the claims are not patentable over the prior art. *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

11. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukushima in combination with Onouchi as applied to claim 10 above, and further in view of Pasin (US Patent No. 3,664,963).

12. Fukushima and Onouchi fail to teach the re-dispersing of the dispersed enzyme/polyol solution into a polymer solution containing a high molecular weight polyol. Hence, attention is directed towards the Pasin reference, which discloses a process for encapsulating an active material in a shell composition. Specifically, Pasin teaches that polyglycols with a high molecular weight (about 2,000) are suitable for desolventizing capsule compositions in which an organic solvent is employed. Pasin discloses that a preferred polyglycol is polyethylene glycol (2:48-62,4:44-63).

13. Fukushima and Onouchi both teach the encapsulation of core enzymatic substances such as hydrolases (Fukushima 3:19-22, Onouchi 4:5-29).

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14. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to first dissolve a core enzymatic substance in a low molecular weight polyol solution and subsequently add a polymeric solution containing a high molecular weight polyol, in the microcapsule formation process of Fukushima in combination with the teachings of Onouchi, and further in view of the teachings of Pasin in order to readily desolventize the organic solvent utilized to form the microcapsule.

15. In reference to the limitations regarding the molecular weight of both the low and high molecular weight polyols, it is noted that the low molecular weight polyol of Onouchi has an average molecular weight of 1,000 (col.14, lines30-31), and the high molecular weight polyol of Pasin has molecular weight of 2,000. Hence the combination of the references, as discussed above, meets the claimed limitations.

16. In reference to the claimed functions of the low and high molecular weight polyols, it is noted that the polyols discussed in the above rejection can function as disclosed in the prior art, and are additionally capable of performing the claimed function. Support is provided from the fact that the claimed polyols and those of the prior art are substantially identical, thus are capable of performing substantially identical functions.

### ***Response to Arguments***

17. The examiner has thoroughly considered applicants remarks and the references applied in the rejection, and has concluded that the references provide sufficient motivation to arrive at the claimed process step.

18. It is noted that applicant has previously argued that the reference fails to show that the core material is both an oil-soluble and water-soluble material. However, the claim language as constructed and given the broadest reasonable interpretation does not require that the core material

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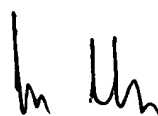
be both oil- and water-soluble, rather the claim reads on one active component that is either oil- or water-soluble. The examiner notes the usage of the term "and" between oil- and water-; however the applicant has used the phrase "at least one active component selected from," which reads discussed interpretation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Saira Haider whose telephone number is (571) 272-3553. The examiner can normally be reached on Monday-Friday from 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Saira Haider  
Examiner  
Art Unit 1711



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